NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, et al., *ex rel.* HOLLY LAMPKIN,	:	
Plaintiffs,	:	Civil Action No. 08-05362 (JAP)
v.	:	**OPINION**
JOHNSON & JOHNSON, INC., VISTAKON, INC., ALCON, INC., ALCON LABORATORIES, INC., and ALLERGAN, INC.,	:	
Defendants.	:	

PISANO, District Judge.

This is a *qui tam* action brought by Plaintiff-Relator Holly Lampkin ("Plaintiff" or "Relator") against Defendants Alcon, Inc. and Alcon Laboratories, Inc. (collectively, "Defendants").[1] Plaintiff alleges that Defendants violated the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA") by promoting an ocular antibiotic to doctors for uses not approved by the FDA and by paying doctors kickbacks to induce them to issue prescriptions that were paid for by government healthcare programs. Presently before the Court is Defendants' Motion to Dismiss the First Amended Complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6). Plaintiff opposes the Motion to Dismiss and has filed a Cross-Motion to Amend. The Court decides these matters without oral argument pursuant to Federal Rule of Civil Procedure 78. For

[1] Defendants Johnson & Johnson, Inc. and Vistakon, Inc. were dismissed from the case by Order dated November 5, 2012 (dkt. entry no. 48). Defendant Allergan, Inc. was dismissed by Order dated December 14, 2012 (dkt. entry no. 54).

the reasons set forth below, the Motion to Dismiss shall be granted and the Cross-Motion to Amend shall be denied.

I. Background

A. Plaintiff's Complaint

The following allegations are summarized from the Complaint,[2] and must be taken as true in deciding this Motion to Dismiss. Defendants are pharmaceutical companies that market and sell a drug called Vigamox, an ocular antibiotic, throughout the United States. Plaintiff-Relator Holly Lampkin was employed by Johnson & Johnson, Inc. ("J&J") – one of Defendants' competitors – as a pharmaceutical sales representative from 2001 to 2008. Plaintiff alleges that during her time as a sales representative at J&J, she became aware that Defendants regularly engaged in the practice of illegally marketing Vigamox for off-label uses.

Plaintiff alleges that Vigamox is FDA-approved for the treatment of conjunctivitis only but Defendants knowingly promote the sale and use of Vigamox nationwide for use as a prophylactic antibiotic, in violation of the Food, Drug and Cosmetics Act, 21 U.S.C. § 331(a); 21 U.S.C. § 352(f). Plaintiff claims that Defendants engage in such off-label promotion because it is very profitable. In fact, she claims that 99% of the sales of Vigamox (and other drugs in its class) on the "national market" are for off-label uses. Plaintiff further alleges that the vast majority of the off-label uses of Vigamox are not medically necessary. She contends that fraudulent claims are submitted to federal and state Medicaid programs, seeking reimbursement for the use of Vigamox for off-label, medically unnecessary purposes.

[2] The operative complaint in this case is currently the First Amended Complaint. Therefore, references to the "Complaint" in this Opinion refer to the First Amended Complaint. Plaintiff also seeks leave to file a Second Amended Complaint, which is discussed below.

Plaintiff further alleges that Defendants violated the Federal Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b)(1) and (2) by paying kickbacks to doctors nationwide to induce them to prescribe Defendants' products. In particular, Plaintiff asserts that Defendants regularly provide physicians with free surgical kits and sell surgical equipment to them at a discounted rate to encourage them to write prescriptions for Vigamox. Plaintiff alleges that reimbursement claims for these drugs are then submitted to government healthcare programs, in violation of these programs' payment conditions, which require doctors' compliance with the Anti-Kickback Act.

B. Defendants' Motion to Dismiss

Defendants move to dismiss Plaintiff's Complaint on three grounds. First, they argue that Plaintiff fails to plead fraud with the particularity, as required by Fed. R. Civ. P. 9(b). Specifically, they contend that the Complaint does not provide any details regarding when or where the fraudulent behavior purportedly occurred and fails to identify specific employees of Defendants that engaged in the fraud. They further assert that Plaintiff does not provide adequate detail regarding the allegedly fraudulent claims that were submitted to the government.

Next, Defendants argue that Plaintiff's allegations fail to state a claim under Fed. R. Civ. P. 12(b)(6). They contend that the Complaint does not demonstrate that any claims submitted to government healthcare programs were actually false or fraudulent. That is, Plaintiff does not allege that the claims were in fact for a drug other than Vigamox or were prescribed for a reason other than what was stated on the claim. Nor does Plaintiff allege that Defendants made any false or misleading statements to health care professionals, which caused them to prescribe the drug for an off-label use. In addition, Defendants argue that Plaintiff cannot state a claim for conspiracy because she has not alleged any facts regarding the purported agreement to commit fraud.

Finally, Defendant Alcon, Inc. also seeks to dismiss the Complaint under Fed. R. Civ. P. 12(b)(5), arguing that it was not properly served with the Summons and Complaint. In particular, Alcon, Inc. contends that Plaintiff attempted to serve Alcon, Inc. through an entity called CT Corporation, but CT Corporation was never authorized to accept service on behalf of Alcon, Inc, a Swiss corporation.

C. Plaintiff's Cross-Motion to Amend

Plaintiff opposes the Motion to Dismiss and seeks leave to amend the Complaint. She argues that the Complaint adequately states a claim against Defendants, but to the extent it does not, the Second Amended Complaint ("SAC") – which is attached to her Motion – cures any purported pleading deficiencies. In particular, the SAC provides additional information regarding specific doctors that prescribed Vigamox for off-label uses and the claims that were submitted to the government based on such prescriptions. It also contains information regarding the surgical kits and donations that Defendants purportedly provided to doctors as kickbacks.

Plaintiff also requests that she be permitted to substitute Novartis AG (the successor-in-interest to Alcon, Inc.) for Alcon, Inc. in the SAC and effect service on Novartis AG.

Defendants oppose the Motion to Amend, arguing that allowing Plaintiff to amend the Complaint would cause undue delay and would be futile because the SAC fails for the same reasons as the Complaint. They further assert that Plaintiff's insufficient service on Alcon, Inc. cannot be cured by substituting Novartis AG. The Court addresses these arguments below.

II. Standard of Review

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Under Federal Rule of Civil Procedure 12(b)(6), a court may grant a motion to dismiss if the complaint fails to state a

claim upon which relief can be granted. In deciding a Motion to Dismiss, courts must first separate the factual and legal elements of the claims, and accept all of the well-pleaded facts as true. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). All reasonable inferences must be made in the Plaintiff's favor. *Nami v. Fauver*, 82 F.3d 63, 65 (3d Cir. 1996); *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384 (3d Cir. 1994).

In 2007, the Supreme Court refashioned the standard for addressing a motion to dismiss under Rule 12(b)(6). *See Bell Atl. Corp. v. Twombly,* 550 U.S. 544 (2007). The *Twombly* Court stated that "a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" *Id.* at 555 (internal citations omitted); *see also Baraka v. McGreevey,* 481 F.3d 187, 195 (3d Cir. 2007). More recently, the Supreme Court has emphasized that, when assessing the sufficiency of a civil complaint, a court must distinguish factual contentions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In addition, Federal Rule of Civil Procedure 9(b) requires that "in all averments or fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally. Fed. R. Civ. P. 9(b). Rule 9(b)'s heightened pleading standard for fraud claims is meant "to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Seville Indus. Mach. v. Southmost Mach.*, 742 F.2d 786, 791 (3d Cir. 1984). In general, the complaint must describe the "who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Props. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (citations and quotations omitted).

III. Legal Discussion

Plaintiff filed this action as a *qui tam* relator under 31 U.S.C. § 3730(b), which provides that a private person may bring an action on behalf of the government to enforce the FCA. Plaintiff alleges violations of: (1) 31 U.S.C. § 3729(a)(1) (presentation of false claims); (2) § 3729(a)(2) (making or using a false record or statement to cause a claim to be paid); and (3) § 3729(a)(3) (conspiracy). Defendants have moved to dismiss on three grounds: (1) the Complaint fails to plead fraud with particularity under Rule 9(b); (2) the Complaint fails to state a claim under Rule 12(b)(6); and (3) Defendant Alcon, Inc. was not properly served with the Complaint. Because the Court finds that the Complaint fails to plead fraud with particularity and to state a claim for conspiracy, it will not address Defendants' remaining arguments.

A. False Statement Claims

To state a claim under § 3729(a)(1), a plaintiff must plead three elements: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004) (citations omitted). To prove a claim under § 3729(a)(2), "plaintiff must also show that the defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved. *Id.*

The Third Circuit has established that FCA claims must be pleaded with particularity in accordance with Federal Rule of Civil Procedure Rule 9(b). *See id.* at 242 n.9. A plaintiff may satisfy that requirement in two ways. *Lum v. Bank of Am.*, 361 F.3d 217, 224 (3d Cir. 2004). First, a plaintiff can meet the requirement "by pleading the date, place or time of the fraud." *Id.* Second, a plaintiff may use an "alternative means of injecting precision and some measure of

substantiation into their allegations of fraud." *Id.* (citing *Seville Indus.*, 742 F.2d at 791). In general, the complaint "must allege who made a misrepresentation to whom and the general content of the misrepresentation." *Id.*; *see also Rockefeller Ctr.*, 311 F.3d at 217. At a minimum, Rule 9(b) requires "that the plaintiff identify the speaker of allegedly fraudulent statements." *Klein v. Gen. Nutrition Co., Inc.*, 186 F.3d 338, 345 (3d Cir. 1999). Here, Plaintiff's Complaint fails to meet this heightened pleading standard.

In the Complaint, Plaintiff alleges that Defendants promoted their drug for off-label purposes and paid kickbacks to doctors in the form of free surgical kits and discounts on surgical equipment. Yet, her allegations of the purportedly false claims that were submitted to the government are vague and conclusory. For example, Plaintiff states that Defendants marketed Vigamox for off-label purposes, certain of which are not medically necessary, and provided surgical kits and discounted medical equipment to doctors. Plaintiff then concludes that as a result of Defendants' conduct, "defendants knowingly caused false and/or fraudulent claims to be submitted to the United States and the State Medicaid programs and caused other U.S. Government sponsored health insurance and health care programs and providers to purchase defendants' respective FQ drugs for unapproved uses." However, she provides absolutely no factual support for this conclusion, which is insufficient under Rule 9(b). *See Rockefeller Ctr.*, 311 F.3d at 216 (Plaintiff "must accompany [her] legal theory with factual allegations that make [her] theoretically viable claim plausible.") (citations omitted).

Indeed, Plaintiff does not identify a single doctor that prescribed Vigamox for an off-label use, much less one who submitted a claim for reimbursement to the government. Nor does she identify a single instance of Defendants' alleged off-label promotion. The Complaint makes no mention of how Plaintiff knows that Vigamox was marketed and prescribed for off-label

purposes, but instead baldly states that it was. The Complaint also baldly states that reimbursement claims were submitted to the government based on such off-label prescriptions, but provides no factual support for these allegations. The Complaint therefore falls far short of what is required to plead a FCA claim with particularity. *See, e.g, United States ex rel. Piacentile v. Sanofi Synthelabo, Inc. et al.*, 2010 WL 5466043, at *8-9 (D.N.J. 2010) (finding that complaint alleging violations of FCA did not satisfy Rule 9(b) where plaintiff alleged that pharmaceutical companies promoted their drugs off-label and paid kickbacks to doctors but did not allege that doctors actually prescribed the drugs or allege that reimbursement claims were actually submitted to the government); *Sweet v. TMI Mgmt. Sys.*, 2008 WL 724275, at *3 (D.N.J. 2008) (dismissing FCA claims under Rule 9(b) where plaintiff "vaguely alleged" the time period and place of the fraud but "d[id] not identify any persons involved in the alleged fraud or any discrete acts that make up the purported pattern of activity.").

The proposed SAC likewise fails to plead an FCA claim with the requisite particularity. Although the SAC contains allegations about specific doctors that prescribed Vigamox during a certain time period (July 2008) to support the claim that Defendants marketed the drug for off-label uses, Plaintiff again fails to identify any particular instance of off-label prescriptions. Instead, she asks this Court to infer that certain named doctors must have prescribed Vigamox for off-label purposes based solely on the fact that these doctors wrote a number of Vigamox prescriptions during July 2008 and that the vast majority of Vigamox sales in the "national market" are for non-FDA-approved uses. Such an inference is a step too far, however, particularly where Plaintiff does not allege that any of these prescriptions were written for government healthcare patients. Nor does Plaintiff identify any examples of specific false claims that were made to the government based on these Vigamox prescriptions. *See ex. rel. Wilkins v.*

United Health Grp., 659 F.3d 295, 308 (3d Cir. 2011) (noting that Rule 9(b) may require a plaintiff to plead specific instances of false claims made to the government); *see also U.S. ex. rel. Nathan v. Takeda Pharm., N. Am., Inc.*, 707 F.3d 451, 456-57 (4th Cir. 2013) ("[T]he particularity requirement of Rule 9(b) does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.").

Similarly, with respect to the alleged kickback scheme, the SAC identifies several doctors who received surgical kits or discounted surgical equipment from Defendants and who also prescribed Vigamox during July 2008. However, she does not allege that these prescriptions were for off-label uses or identify any specific false claims that were submitted to the government.[3] Nor does she provide adequate factual support for her assertion that these doctors only prescribed Vigamox as a result of Defendants' provision of kickbacks.[4] Instead, she simply alleges in conclusory fashion that these doctors wrote Vigamox prescriptions while they were "in receipt of discounted surgical equipment [and] surgical kits" and that a portion of these

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[3] One of the doctors who allegedly received kickbacks – Dr. Todd Brockman – is one of the doctors that Plaintiff claims prescribed Vigamox for off-label purposes. However, as discussed above, Plaintiff fails to identify any particular instance of such an off-label prescription or a claim submitted to the government based on that prescription.

[4] Plaintiff does allege that two doctors, Dr. David Parke and Dr. David Jackson, made statements to her regarding their purported obligation to prescribe Vigamox (as opposed to similar drugs from Defendants' competitors) because of Defendants' donations and kickbacks. However, Plaintiff again fails to allege any instance of off-label prescriptions by either of these two doctors or any specific instances of such claims being submitted to the government.

While Plaintiff alleges that roughly 30% of prescriptions for all drugs in this class in Oklahoma City were submitted to the government in July 2008, that is insufficient to establish that these two doctors prescribed Vigamox as a result of Defendants' kickbacks and then submitted claims for reimbursement to the government. *See Takeda*, 707 F.3d at 459 (applying generalized statistics to the prescribing habits of named defendants would require the court to draw an "implausible inference" linking the general statistics to the particular prescriptions at issue).

prescriptions were then submitted to the government for reimbursement. Plaintiff's vague allegations fail to provide the who, what, when, where and how of Defendants' alleged fraud and are inadequate to place them on notice of the exact misconduct with which they are charged. *See Sanofi*, 2010 WL 5466043, at *8-9 (dismissing FCA claims under Rule 9(b) where plaintiff alleged that certain doctors prescribed a drug for off-label uses resulting in the submission of false claims to the government because the allegations of claims submitted to the government and off-label prescriptions were conclusory). Plaintiff's false statement allegations are insufficient to plead an FCA claim under Rule 9(b) and will be dismissed.

B. Conspiracy Claim

To plead a claim for conspiracy under § 3729(a)(3), a plaintiff must allege "(1) a conspiracy to get a false or fraudulent claim allowed or paid; and (2) an act in furtherance of the conspiracy." *U.S. ex rel. Atkinson v. PA. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir. 2007). Critically, "[t]he essence of a conspiracy under the Act is an agreement between two or more persons to commit fraud." *Sanofi*, 2010 WL 5466043, at *9 (internal quotations omitted).

Here, Plaintiff's allegations fall short of what is required to state a claim for conspiracy. In particular, Plaintiff has failed to allege any meeting of the minds between Defendants and the doctors who prescribed their drugs. Instead, she merely alleges that Defendants marketed their drugs for off-label purposes and paid kickbacks to doctors to induce them to prescribe Defendants' drugs. Such vague and conclusory allegations are insufficient to plead a claim for conspiracy. *See id.* at *9 (dismissing claim for conspiracy under FCA where plaintiff made allegations about doctors "who received speaker's fees and other purportedly improper benefits" from defendants, but failed to allege an agreement between doctors and defendants).

The SAC similarly fails to plead a claim for conspiracy. While it adds more detailed allegations regarding specific doctors who received Defendants' promotional materials and so-called kickbacks, it nonetheless fails to allege any actual agreement between Defendants and such doctors to use "a false record or statement." This defect is fatal to Plaintiff's conspiracy claim. *See id.; see also United States ex. rel. Pilecki-Simko v. Chubb Inst.*, 2010 U.S. Dist. LEXIS 27187, at *36-37 (D.N.J. 2010) (dismissing FCA claim for conspiracy because relator did not allege that defendant had an agreement with any of its corporate parents to use a false record or statement that would have a material effect on the government's decision to pay); *United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 124 (W.D. Pa. 2006) (dismissing conspiracy allegations because they were "conclusory in nature" and "fail[ed] to properly allege an agreement, which is the 'essence' of the conspiracy claim") (citations omitted). Accordingly, Plaintiff's conspiracy allegations fail to state a claim and will be dismissed.

C. Plaintiff's Cross-Motion to Amend

Plaintiff seeks leave to amend the Complaint, arguing that the SAC cures any purported pleading deficiencies in the Complaint. Under the Federal Rules of Civil Procedure, the Court may grant leave to amend a complaint, and should do so "when justice so requires." Fed. R. Civ. P. 15(a)(2). The Supreme Court has encouraged generous application of this rule generally, allowing leave to amend "in the absence of evidence of 'undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowing the amendment [or] futility of amendment." *United States v. Duffus*, 174 F.3d 333, 337 (3d Cir. 1999) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). An amendment is futile if it "is frivolous or advances a claim or defense that is legally insufficient on its face." *Harrison Beverage Co. v. Dribeck Importers,*

Inc., 133 F.R.D. 463, 468 (D.N.J. 1990) (internal quotations and citations omitted). In determining whether an amendment is "insufficient on its face," the Court employs the Rule 12(b)(6) motion to dismiss standard. *See Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000).

Although Plaintiff's motion to amend the complaint was apparently filed in response to Defendant's motion to dismiss, the proposed SAC does not contain sufficient additional or clarifying factual matter to survive a motion to dismiss. As discussed above, an analysis shows that Plaintiff has failed to plead plausible claims of fraud under the FCA. While the SAC includes certain additional factual allegations in support of her claims, they are still inadequate to plead a claim for violation of the FCA. Therefore, the Court finds that amendment of the Complaint would be futile and will deny Plaintiff's motion to amend.

IV. Conclusion

For the foregoing reasons, Defendants' Motion to Dismiss will be granted and Plaintiff's Cross-Motion to Amend will be denied. An appropriate Order follows.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

Dated: May 31, 2013